



DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, and 173

[Docket No. PHMSA-2016-0014 (HM-224I)]

RIN 2137-AF20

Hazardous Materials: Enhanced Safety Provisions for Lithium Batteries Transported by Aircraft (FAA Reauthorization Act of 2018)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule revises the Hazardous Materials Regulations for lithium cells and batteries transported by aircraft and is consistent with the previously published Interim Final Rule, which responded to congressional mandates; prohibited the transport of lithium ion cells and batteries as cargo on passenger aircraft; required lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and limited the use of alternative provisions for smaller lithium cell or battery shipments to one package per consignment. In response to comments, this final rule provides editorial amendments and modification of certain provisions including marking requirements, requests for an extension on the compliance date, and exception for lithium cells or batteries used for medical devices with approval by the Associate Administrator.

DATES: This final rule is effective on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

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I. Executive Summary

The safe transport of lithium batteries by air has been an ongoing concern due to the unique challenges they pose to safety in the air transportation environment. Unlike most other hazardous materials, lithium batteries have a dual hazard of chemical and electrical. This combination of hazards, when involved in a fire, has the potential to create a scenario that exceeds the fire suppression capability of an aircraft and lead to a catastrophic failure of the aircraft.

The Pipeline and Hazardous Materials Safety Administration (PHMSA) issued an interim final rule (IFR)¹ to amend the hazardous materials regulations (HMR; 49 CFR parts 171-180) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge (SOC) on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment. The IFR amendments predominately

¹ 84 FR 8006 (Mar. 6, 2019).

affected air carriers (both passenger and cargo-only) and shippers that offer lithium ion cells and batteries for transport as cargo by aircraft. The IFR amendments neither restricted passengers or crew members from bringing electronic devices containing lithium cells or batteries aboard aircraft nor restricted the air transport of lithium ion cells or batteries when packed with or contained in equipment. The IFR also fulfilled the section 333 mandates in the Federal Aviation Administration (FAA) Reauthorization Act of 2018 and amended the HMR to allow shipments of not more than two replacement lithium cells or batteries specifically used for medical devices as cargo on passenger aircraft—with the approval of the Associate Administrator—to accommodate persons in areas potentially not serviced daily by cargo aircraft. Furthermore, these lithium batteries may be excepted from the SOC requirements when they meet certain provisions.

As discussed in further detail in this final rule (see IV. Section-by-Section Review), PHMSA amends certain sections of the HMR in response to public comments received to the IFR. Overall, the comments to the IFR were supportive of PHMSA's action; however, PHMSA did receive a few comments seeking further clarification or revisions to the IFR which PHMSA also addresses in this final rule. Specifically, PHMSA revises the HMR to better ensure that it reflects the original intent of the IFR, particularly in the alignment with the lithium battery transportation requirements with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air (Technical Instructions). In addition, PHMSA clarifies the implementation of the exception, with approval of the Associate Administrator, for air transportation of lithium batteries intended for use in medical devices. Finally, PHMSA responds to comments related to the marking requirement for smaller lithium ion cells or batteries transported by modes other than aircraft and addresses a safety risk associated with lithium batteries transported in overpacks.

A final regulatory impact analysis (RIA) is included in the docket for this rulemaking and supports the amendments made in this rulemaking. PHMSA examined the benefits and costs of PHMSA action in this rulemaking using the final rule as a baseline as shown in Table 1 below.

Table 1: Summary of Incremental Costs and Benefits for Lithium Battery Provisions from the Baseline

Provision	Benefits	Unquantified Costs	10-Year Quantified Cost (7%)
State of Charge	None	None	N/A
Consignment Limit	None	None	N/A
Lithium Battery Prohibition as Cargo on Passenger Aircraft	None	None	N/A
Marking overpacks with statement of prohibition from transport aboard passenger aircraft or a CAO label*	None	None	\$1,574,680
Total			10-Year: \$1,574,680
			Annualized: \$224,199
<p>*PHMSA's baseline assumes compliance with the IFR, including marking requirements. PHMSA did not previously quantify the costs and benefits of the requirement for packages shipped via all modes except air to be marked with a statement of prohibition from transportation on passenger aircraft or a CAO label. Thus, PHMSA quantifies the costs associated with this requirement and attributes them to the IFR and not the final rule (see Appendix I: Methodology for Estimating Lithium Battery Shipments). There are no quantifiable benefits associated with this requirement. PHMSA expects that the requirement will ensure regulatory consistency. Further, the communication is necessary to ensure safe transportation, as it will prevent smaller lithium cells and batteries, including those packed with or contained in equipment greater than 5 kg, from being transported as cargo on passenger aircraft.</p>			

PHMSA estimates the present value of costs at about \$1.6 million over 10 years and about \$0.2 million annualized (at a 7 percent discount rate).

PHMSA expects adoption of these amendments will improve the safety of shipments of lithium batteries, which are expected to increase as the use of lithium batteries in the transportation sector and other economic sectors increases in the years ahead. The final rule also provides regulatory consistency and harmonization with international standards, which reduces delays and interruptions in the global transportation of lithium batteries.

II. Background

PHMSA issued an IFR to amend the HMR) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge (SOC) on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment. The IFR amendments predominately affected air carriers (both passenger and cargo-only) and shippers that offer lithium ion cells and batteries for transport as cargo by aircraft. The IFR amendments did not affect requirements for passenger and crew personal items containing lithium cells or batteries aboard aircraft, nor restricted the air transport of lithium ion cells or batteries when packed with or contained in equipment. The IFR fulfilled the section 333 requirement in the FAA Reauthorization Act of 2018 to allow shipments of not more than two replacement lithium cells or batteries specifically used for medical devices as cargo on passenger aircraft—with the approval of the Associate Administrator—to accommodate persons in areas potentially not serviced daily by cargo aircraft. Furthermore, these lithium batteries may be excepted from the SOC requirements when they meet certain provisions. See “Section II. Comment Discussion; Exception for Medical Devices” for further discussion.

The IFR was necessary to address an immediate safety hazard and meet a statutory requirement to harmonize the HMR with emergency amendments to the 2015-2016 edition of the ICAO Technical Instructions. The serious public safety hazards associated with lithium battery transportation and the statutory deadline in the FAA Reauthorization Act of 2018 necessitated the immediate adoption of these standards in accordance with the APA. 5 U.S.C. 553(b)(3)(B) and 553(d)(3). The potential for a catastrophic loss of an aircraft, especially a passenger aircraft carrying lithium battery cargo, the need for harmonization of the HMR with emergency amendments to the ICAO Technical Instructions, and the statutory deadline in the FAA

Reauthorization Act of 2018² provided compelling justification to adopt these changes into the HMR immediately without prior notice and comment.

The IFR, including the APA good cause determination, was supported by the findings of lithium battery research conducted by the FAA's William J. Hughes Technical Center (FAA Technical Center), the National Transportation Safety Board (NTSB), and several other well-respected academic sources on lithium batteries and their hazards with respect to amendments that were adopted. The FAA Technical Center's research found that lithium batteries subject to certain conditions could result in adverse events, such as smoke and fire, that could impair the safe operation of the aircraft. Specifically, they found that in a lithium battery fire, flammable gases could collect, ignite, and ultimately exceed the capabilities of an aircraft's fire suppression system. See "Section III. Need for the Rule" of the IFR for further explanation of the testing and research that supports this finding. The ICAO also recognized these dangers and adopted additional measures into the international air transport standards, which went into effect on April 1, 2016. The potential for a catastrophic loss of an aircraft, especially a passenger aircraft carrying lithium battery cargo, the need for harmonization of the HMR with emergency amendments to the ICAO Technical Instructions, and the statutory deadline in the FAA Reauthorization Act of 2018 provided compelling justification to adopt these changes into the HMR immediately without prior notice and comment.

In this final rule, PHMSA responds to public comments received to the IFR and revises the HMR based on those comments. Specifically, PHMSA revises the HMR to better align the lithium battery transportation requirements with the ICAO Technical Instructions. In addition, PHMSA clarifies the implementation of the exception, with approval of the Associate Administrator, for lithium batteries intended for use in medical devices. PHMSA also responds

² PHMSA's finding of good cause was based on the impracticability of providing the public with notice-and-comment while attempting to comply with the 90-day statutory rulemaking mandate in the FAA Reauthorization Act of 2018, Pub. L. 115-254 (October 5, 2018, FAA Reauthorization Act of 2018). PHMSA's compliance with the statutory deadline was negatively impacted by a lapse in funding from December 22, 2018, through January 25, 2019, that affected PHMSA, FAA, and other government agencies.

to comments related to the marking requirement for smaller lithium ion cells or batteries transported by modes other than aircraft.

III. IFR Comment Discussion

In response to the March 6, 2019, IFR, PHMSA received comments from the following organizations and individuals, which are listed in order of docket submission:

- Linda Seubert (PHMSA-2016-0014-0005 and -0006)
- Kevin McAuley (PHMSA-2016-0014-0007)
- The Rechargeable Battery Association (PRBA) (PHMSA-2016-0014-0010 and -0028)
- Anonymous (PHMSA-2016-0014-0012)
- Joel Gregier (PHMSA-2016-0014-0014 and -0015)
- Medical Device Battery Transport Council (MDBTC) (PHMSA-2016-0014-0016)³
- Infotrac (PHMSA-2016-0014-0017)
- Sandra Harding (PHMSA-2016-0014-0018)
- Michael Stoddard (PHMSA-2016-0014-0019)
- Anonymous (PHMSA-2016-0014-0020)
- Taylor Cu (PHMSA-2016-0014-0021)
- Justin Davis (PHMSA-2016-0014-0022)
- Logistics Supply Chain Coalition (LSCC) (PHMSA-2016-0014-0023)
- Anonymous (PHMSA-2016-0014-0024)
- United Airlines (PHMSA-2016-0014-0025)
- Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA) (PHMSA-2016-0014-0026)
- Retail Industry Leaders Association (RILA) (PHMSA-2016-0014-0027)

³ Since submitting comments to the IFR, the Medical Device Battery Transport Council has changed their name to the Medical Device Transport Council.

- United Parcel Service (UPS) (PHMSA-2016-0014-0029)
- Air Line Pilots Association, International (ALPA) (PHMSA-2016-0014-0030)
- Alaska Air Carriers Association (AACA) (PHMSA-2016-0014-0031)

Below, PHMSA addresses comments to the IFR, including a brief synopsis and response. Additional comments are discussed in “Section III. Section-by-Section Review.” Those comments not addressed herein were considered beyond the scope of the rulemaking.

A. Harmonization with International Standards

The IFR intended to align the HMR with international air transport standards for the transportation of lithium cells and batteries, as mandated in the FAA Reauthorization Act of 2018, specifically to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent SOC on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment.

Commenters were generally supportive of this rulemaking. Out of 23 comments received (one duplicate), 15 commenters expressed general support, three (3) expressed opposition based on certain provisions, and the remainder sought amendment of certain provisions to improve clarity or avoid unintended consequences. Specifically, commenters supported the rulemaking’s alignment with international standards and acknowledged the potential risk that lithium ion cells and batteries pose in passenger and cargo aircraft transportation.

B. Marking Requirements for Transport Modes Other than Aircraft

The IFR prohibited the transportation of lithium ion cells and batteries as cargo on passenger aircraft. Prior to publication of the IFR, only lithium metal cells and batteries were prohibited from transportation as cargo on passenger aircraft. For smaller lithium metal cells and batteries, the HMR required that these packages display a statement of prohibition or the cargo

aircraft only (CAO) label, regardless of the mode of transportation. Because the IFR expanded the passenger aircraft transportation prohibition to include lithium ion cells and batteries, PHMSA also expanded the smaller lithium metal cell and battery marking or labeling requirement to include smaller lithium ion cells or batteries. PHMSA expected that the expansion of the hazard communication requirement would help to ensure that smaller lithium ion cells and batteries would not be accidentally transported as cargo on passenger aircraft. PHMSA notes that internationally—i.e., under the 2015-2016 ICAO Technical Instructions, and later editions—lithium ion battery packages are required to be labeled with the CAO label. See ICAO Technical Instructions Packing Instruction 965.

PHMSA received several comments that opposed this requirement, particularly when the package of smaller lithium ion cells and batteries is transported by a mode other than aircraft (e.g., highway, rail, and/or vessel), citing additional transport burden and costs. While PHMSA acknowledges the additional burden, if there is no indication on the package that the package is forbidden for transport aboard passenger aircraft, there is a higher likelihood that these packages will be placed on a passenger aircraft. Although packages shipped by highway, rail, and/or vessel may be part of a closed transportation system, a package of smaller lithium ion cells or batteries that is only marked with the lithium battery mark—without an indication that it is forbidden for passenger aircraft—could still find its way into the air transportation stream. For example, recent FAA data shows that there have been approximately 306 reported incidents where lithium cells and batteries forbidden aboard passenger aircraft have been transported aboard passenger aircraft. As discussed in the IFR, based on past incidents and the inherent potential danger of lithium ion battery thermal runaway events, there is a safety reason to reduce the likelihood that lithium ion batteries are placed on passenger aircraft as cargo. Therefore, PHMSA and FAA expect that the marking, which serves as a clear visual indication that the package is forbidden for transport on passenger aircraft, will help prevent air operator workers from inadvertently loading lithium ion battery packages as cargo on passenger aircraft. Because of this safety

concern, PHMSA opted to maintain the requirement that packages of smaller lithium ion cells and batteries must be marked with an indication that the package is forbidden for transport aboard passenger aircraft or labeled with the CAO label. However, to communicate fully the burdens associated with this requirement, PHMSA quantified the costs attributable to the IFR in Appendix 11 of the final RIA.

PHMSA also received suggestions for potential exceptions from the forbidden for passenger air mark or CAO label requirement for packages of smaller lithium cells and batteries. For example, COSTHA, PRBA, Alaska Air Carriers Association, RILA and other commenters recommended that PHMSA provide an exception from this mark or label requirement for packages of smaller lithium ion cells and batteries transported only by highway on dedicated trucks (i.e., a private fleet) that are not transferred between motor carriers. PHMSA acknowledges that there may be some circumstances where the potential for packages to be placed on passenger aircraft is minimized considerably, however, no exceptions are adopted. As mentioned previously, it is vital to ensure that lithium ion cells and batteries are not placed on a passenger aircraft as cargo in the interest of safe transportation. Additionally, as there are no exceptions from this marking or labeling requirement for smaller lithium metal cells and batteries, the addition of an exception for only lithium ion cells and batteries will create an inconsistency in the application of the HMR and may result in uncertainties when complying with the HMR lithium battery requirements. The availability of the special permit program allows a person to present its case via application for an exemption from the mark or label requirement in accordance with 49 CFR part 107, subpart B. This process of issuing a special permit on a case-by-case basis allows PHMSA to maintain oversight by way of specific, tailored operational and safety controls that will prevent lithium ion batteries from being transported on passenger aircraft. For example, PHMSA has issued two special permits⁴ that exempt the § 173.185(c)(1)(iii) marking or labeling requirements, subject to certain operational or safety

⁴ See DOT Special Permits 16413 and 20480.

controls. The special permits were granted to Amazon.com, Inc. and Inmar Supply Chain Solutions, LLC. The operational and safety controls included modal restrictions to highway and rail. The special permits also authorized the transportation of lithium batteries to designated locations only and required markings on overpacks such as “OVERPACK,” special permit number, the words “Packages must remain within this overpack during transport,” and the words “LITHIUM BATTERIES – FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.” These special permit operational and safety controls demonstrated equivalent levels of safety while providing relief from certain HMR requirements while also requiring package marking to ensure lithium battery packagings are not unintentionally placed as cargo on passenger aircraft.

Commenters also noted that PHMSA did not revise the sections of the HMR associated with authorization and use of international standards and regulations (i.e., §§ 171.12 (North American shipments), 171.24 (additional requirements for use of the ICAO Technical instructions), and 171.25 (additional requirements for use of the International Maritime Dangerous Goods (IMDG) Code)) to mirror the changes made in § 173.185. Specifically, commenters noted that §§ 171.12 and 171.24 did not include the restriction of lithium ion cells and batteries from transportation on passenger aircraft and §§ 171.12, 171.24, and 171.25 did not include the additional marking or labeling requirement for smaller lithium ion cells and batteries, as currently specified for smaller lithium metal cells and batteries. Additionally, COSTHA, Infotrac, MDBTC, PRBA, and Ms. Sandra Harding commented that the smaller lithium ion cell and battery requirement did not align with the IMDG Code or Transport Canada’s Transportation of Dangerous Goods (TDG) Regulations and requested clarification on how the mark or label requirement for smaller lithium ion cells and batteries applies to international shipments. While PHMSA acknowledges that the marking requirement differs, as previously mentioned, PHMSA expects that the requirement will increase the safe transportation of lithium batteries. Furthermore, Part 5;2.4.1.3 of the ICAO Technical Instructions allows for markings required by

other international or national transport regulations in addition to marks required by the ICAO Technical Instructions, provided they are not confused with or conflict with any ICAO prescribed markings.

The absence of the conforming regulatory language for the passenger aircraft restriction and smaller lithium ion cell and battery mark or label requirement was an unintentional omission and PHMSA thanks commenters for bringing it to PHMSA's attention. Therefore, PHMSA adds language to §§ 171.12 and 171.24 to specify that lithium ion cells and batteries are forbidden from transportation as cargo on passenger aircraft. Additionally, PHMSA adds language to §§ 171.12, 171.24, and 171.25 to indicate that smaller lithium ion cells and batteries must be marked with an indication that the package is forbidden for transport aboard passenger aircraft or be labeled with a CAO label. See "Section IV. Section-by-Section Review; Section 171.12," "Section IV. Section-by-Section Review; Section 171.24," and "Section IV. Section-by-Section Review; Section 171.25" for a further discussion on these changes.

Commenters also suggested that PHMSA provide an additional text marking option for smaller lithium cells and batteries without specifically indicating the battery chemistry (i.e., "LITHIUM BATTERIES—FORBIDDEN FOR PASSENGER AIRCRAFT") as lithium battery chemistry (i.e., ion vs. metal) no longer differentiates whether the package may be offered for transportation as cargo on passenger aircraft. PHMSA agrees that this additional option provides greater flexibility, without a reduction in safety. Specifically, this also allows shippers to use preprinted packaging and avoids the need for separate markings if both smaller lithium ion and metal cells and batteries are shipped in the same package. Therefore, PHMSA adds the additional marking option of a general lithium battery indication to § 173.185(c)(3)(iii) as well as §§ 171.24(d)(1)(ii) and 171.25(b)(3).

Lastly, RILA requested clarification that when the § 173.185(c)(1)(iv) marking is applied to a shipment (i.e., a package) of intermediate-sized lithium cells or batteries, the mark or label in § 173.185(c)(1)(iii) is not also required to be displayed. PHMSA did not intend for the mark or

label required by § 173.185(c)(1)(iii) to also apply to packages of lithium batteries marked as specified in § 173.185(c)(1)(iv). Section 173.185(c)(1)(iv) authorizes that when transported only by highway or rail the lithium content limitation in § 173.185(c)(1)(ii) may be increased to 5 g for a lithium metal cell or 25 g for a lithium metal battery and the watt-hour (Wh) rating limitation in § 173.185(c)(1)(i) may be increased to 60 Wh for a lithium ion cell or 300 Wh for a lithium ion battery. This allowance is authorized contingent on the outer package being marked: “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.” Because this outer package marking provides an indication that the lithium batteries may not be transported by aircraft or vessel, the marking in § 173.185(c)(1)(iii), which indicates that the package is forbidden for passenger aircraft, would be redundant and the CAO label option would be confusing because the authorize increase in lithium content is not allowed for aircraft transportation (both passenger and cargo). To ensure that there is no confusion, PHMSA adds an indication in § 173.185(c)(1)(iv) to specify that a shipment of lithium cells and batteries marked with the forbidden for transport aboard aircraft and vessel statement does not need to display the marking required in § 173.185(c)(1)(iii).

C. Compliance Date

PHMSA received five comments that PHMSA delay the compliance date⁵ for the marking or labeling requirement in § 173.185(c)(1)(iii) for modes other than aircraft, including requests to issue a Statement of Enforcement Discretion. One of these comments was submitted as a direct letter to the Department of Transportation (DOT) by PRBA, MDBTC, Dangerous Goods Advisory Council (DGAC), Power Tool Institute, National Electrical Manufacturers Association, Outdoor Power Equipment Institute, and International Vessel Operators Dangerous Goods Association.⁶ PHMSA issued a response to this request on April 4, 2019, in which

⁵ The IFR became effective March 6, 2019. PHMSA received comments with requests for extending the compliance date between four months (i.e., July 1, 2019) and twenty-one months (i.e., December 31, 2020).

⁶ <https://www.regulations.gov/document?D=PHMSA-2016-0014-0010>

PHMSA specified that a transition period was not provided and a Statement of Enforcement Discretion would not be issued.⁷ PHMSA explained that this marking or labeling requirement is essential to ensure smaller lithium ion cells and batteries are not inadvertently transported as cargo by passenger aircraft consistent with the prohibition of the carriage of lithium metal batteries as cargo on passenger aircraft and thus, no transition period is provided (i.e., no delay in compliance date).

PHMSA also received an anonymous comment that PHMSA provide a transition period for the entire rulemaking. The commenter stated that a transition period would assist with rerouting of shipments where a cargo aircraft option does not exist and allow for proper notification of potential delays to customers. While PHMSA acknowledges that the immediate compliance of the IFR may have placed some burden on scheduling and potential delays, immediate compliance ensured continued safety for air transportation as the risks posed by lithium batteries on an aircraft were promptly minimized.

D. Allowance of CAO Label for Modes Other than Aircraft

As previously mentioned, § 173.185(c)(1)(iii) provides a variety of methods to identify that a package is forbidden for transportation by passenger aircraft, which includes use of the CAO label. PRBA, COSTHA, RILA and some anonymous commenters noted that the use of the CAO label should not be authorized when the package is not properly prepared for cargo aircraft (i.e., lithium ion batteries shipped above a 30 percent SOC and not contained in or packed with equipment), as the CAO label is an indication that the package is permitted on cargo aircraft. PHMSA disagrees with the commenters' understanding. The intent of the CAO label is only to provide an indication that the package is forbidden for passenger aircraft. It does not indicate that the package is authorized or has been properly prepared for transport on cargo aircraft. Instead, the CAO label represents that the hazard of the contents of the package are too great of a risk for

⁷ <https://www.regulations.gov/document?D=PHMSA-2016-0014-0032>

transportation in passenger aircraft. This is articulated by the message on the CAO label, which states “FORBIDDEN IN PASSENGER AIRCRAFT.” Therefore, PHMSA maintains that this label can still be used as an appropriate indication that the package of smaller lithium ion cells or batteries is forbidden for transportation aboard passenger aircraft, even if, for example, the batteries do not meet the SOC requirement for transport of lithium ion batteries aboard cargo aircraft.

E. Exception for Medical Devices

In addition to instructing DOT to harmonize lithium battery regulations with the ICAO Technical Instructions, the FAA Reauthorization Act of 2018 instructed DOT to issue limited exceptions to the restrictions on transportation of lithium ion and metal cells and batteries specifically used for a medical device.⁸ PHMSA added paragraph (g) to § 173.185 to provide limited exceptions for the air transportation of medical device batteries, with the approval of the Associate Administrator. PRBA, MDBTC, and AACA all submitted comments related to the regulatory text in paragraph (g).

PRBA asserts that PHMSA’s regulatory text is inconsistent with the intent of the medical device batteries mandate. Specifically, PRBA does not consider the approval requirement outlined in the IFR to be an exception to the HMR’s requirements. MDBTC also asserts that the approval requirement does not constitute an exception, claiming that the legislative intent was “to allow shipments of medical device batteries aboard passenger aircraft in urgent situations and for PHMSA to define the parameters where this exception can be used.” AACA expresses support for MDBTC’s comments, and further states that the legislative intent of the FAA Reauthorization Act of 2018 “must include small and large quantities of lithium ion and lithium metal batteries...in urgent situations.” PRBA, MDBTC, and AACA allege that PHMSA’s approval process for medical device batteries under § 173.185(g) would fail to accommodate

⁸ Pub. L. No. 115-254, § 333, 132 Stat. 3186, 3274.

urgent situations where medical device batteries need to be shipped expeditiously, such as for patients that require urgent medical care. MDBTC and AACA also note that the timeline for the approval process—90 to 120 days—is unrealistic to meet real-world situations when batteries are urgently needed.

PHMSA does not agree with the commenters' description of the legislative intent, and notes that there is no legislative history available to support the commenters' assertions. The regulatory text under § 173.185(g) establishes a process to authorize the transport of medical device batteries consistent with the Act's limited exceptions mandate under Section 333(b)(2), and PHMSA remains confident that the approval process can accommodate urgent shipping needs.

Section 333(b)(1) of the FAA Reauthorization Act of 2018 sets forth that DOT shall consider and either grant or deny, not later than 45 days after receipt, an application submitted in compliance with part 107 of title 49, Code of Federal Regulations, for special permits or approvals for air transportation of lithium ion cells or batteries specifically used by medical devices. Section 333(b)(2) directs DOT to “issue limited exceptions” to the HMR “to allow the shipment on a passenger aircraft of not more than two (2) replacement batteries specifically used for a medical device” if certain conditions are met.

The statutory language does not specify how PHMSA should limit these exceptions, and there is no legislative history available. In the absence of direction from Congress, PHMSA responded to these mandates by authorizing, contingent on the approval of the Associate Administrator, a limited exception of up to two (2) lithium batteries used for medical devices to be transported on passenger aircraft and, as applicable, at an SOC higher than 30 percent, when the intended destination of the batteries is not serviced daily by cargo aircraft. The approval process is subject to an expedited processing period of no longer than 45 days. Under this approval process up to two replacement lithium cells or batteries specifically used for a medical device may be transported as cargo on a passenger aircraft, when approved by the Associate

Administrator and provided the conditions set forth in the Section 333(b)(2) of the FAA Reauthorization Act of 2018 are met. PHMSA also adopted the definition of medical device as used in Section 333(b)(3) of the FAA Reauthorization Act of 2018.

Further, as discussed in the IFR preamble,⁹ even though Section 333(b)(1) of the FAA Reauthorization Act of 2018 references lithium ion batteries and not lithium metal batteries, PHMSA understands the language to also apply to lithium metal batteries because Section 333(b)(2) applies to both lithium ion and lithium metal batteries for medical devices. Therefore, all approvals requested pursuant to § 173.185 are subject to the expedited processing period of no longer than 45 days.

PHMSA's regulatory text complies with the FAA Reauthorization Act of 2018 by: (1) adopting the Act's definition of medical device, (2) setting up an expedited approval process to allow the transport of medical devices on an urgent basis, and (3) implementing packaging requirements mandated in the Act to ensure the safe transportation of each medical device battery that is transported at a SOC greater than 30 percent. Limiting the exception via an approval requirement allows PHMSA to maintain oversight of these lithium battery shipments and address the risks they pose in air transportation, with the aim of ensuring the aircraft's cargo and the aircraft's passengers arrive safely at their destination. To date, PHMSA has received only two approval applications neither of which sought exception from the SOC requirements. These requests were denied due to not making the case for how the requested transport would mitigate risks posed by a lithium battery heat, smoke, or fire event on a passenger aircraft. Based on this experience with approval applications, PHMSA maintains its position that approval oversight is needed.

Additionally, AACA and MDBTC assert that PHMSA's approval process needs to be clarified, including whether each shipment of medical device batteries would require approval. PHMSA understands this viewpoint and provides clarity as follows. When an applicant applies

⁹ 84 FR 8006 at 8019 (Mar. 6, 2019).

for any PHMSA approval—including this type of medical device batteries approval—they may choose to request an approval for a one-time shipment or for recurring shipments, on either a periodic or as needed basis. *See* 49 CFR 107.705(b)(2). Specific to recurring shipments, PHMSA expects that issuing this type of approval will accommodate emergency circumstances because a person who wishes to offer or transport lithium batteries for medical devices will have prior approval before the emergency need occurs.

MDBTC also commented that the expedited approval process should be codified in part 107. PHMSA agrees that the unique procedures for lithium cells and batteries for medical devices in § 173.185(g) should be included in part 107. PHMSA revises §§ 107.709(b) and (f) to reflect the expedited application process found in the FAA Reauthorization Act of 2018. See “Section IV. Section-by-Section Review; Section 107.709” for further detail on the specific revisions to these paragraphs.

Additionally, PHMSA requested comment on certain criteria for this provision, including potential impacts these criteria may have on stakeholders. The following details the criteria, along with a discussion of the comments PHMSA received.

- *Definition of “not more than two replacement lithium cells or batteries.”* PHMSA requested comment on whether the limitation that “not more than two replacement lithium cells or batteries” applies to the number of cells or batteries per package. MDBTC agreed the intent of Section 333(b)(2) of the 2018 FAA Reauthorization Act provision is two cells or batteries per package (and not per shipment or consignment). As this provision minimizes the number of batteries in each package, which reduces the potential for a thermal runaway event in transportation and thus increases safety, PHMSA maintains § 173.185(g) as written such that not more than two (2) lithium cells or batteries are allowed per package.
- *Determination of destination no longer “serviced daily by cargo aircraft”:* PHMSA requested comment on what should be considered to determine when a destination is

no longer “serviced daily by a cargo aircraft.” MDBTC, supported by the AACA, commented that it was not necessary for PHMSA to specify a specific distance to define when a location is no longer serviced daily by cargo aircraft. Furthermore, MDBTC commented that availability of the exception should be based on the need for urgent patient care when other means of transport are unavailable or inappropriate. AACA also stated that the distance should not be a condition of the exception. PHMSA agrees with MDBTC and AACA that “serviced daily by a cargo aircraft” should not be tied to a specified distance, as this will provide greater flexibility for handling unique transport circumstances. It is necessary for the person who wishes to transport the lithium cell or battery for medical devices to demonstrate that the location is not serviced daily by cargo aircraft in their application, as this is a condition for the exception that is articulated in § 173.185(g). PHMSA is also making a conforming revision to add § 107.705(b)(6) to specify that this information must be provided in the approval application.

- *Definition of batteries “required for medically necessary care”*: PHMSA stated that batteries “required for medically necessary care” are batteries that are needed for a medical device that is used by the recipient for medical care and requested comment on stakeholder impact. MDBTC commented that the definition of “required for medically necessary care” is appropriate. PHMSA received no further comment on this subject. Therefore, PHMSA maintains that batteries required for medically necessary care in § 173.185(g) means the batteries are needed for a medical device that is used by the recipient for medical care.

MDBTC and PRBA both commented that PHMSA should harmonize the HMR with Special Provision A334 found in the Supplement to ICAO Technical Instructions for all lithium batteries. MDBTC further stated that this provision would expand the allowance to ship lithium batteries for emergency needs to remote areas in circumstances outside of medical device

transportation. AACA was supportive of MDBTC's comments and further commented that allowances should be made for small quantities of lithium ion cells and batteries to be shipped to remote locations. Special Provision A334 provides guidance to competent authorities on exceptions for lithium cells or batteries to be transported on passenger aircraft when other forms of transport—including cargo aircraft—are impracticable. This special provision identifies specific quantity limits and performance test criteria that can be used to acquire the approval of the State of Origin, the State of the Operator, and the State of Destination. It is unnecessary to adopt this specific language as PHMSA already provides a general approval mechanism for lithium batteries that do not conform to the provisions of the HMR (*see* § 173.185(h)). Finally, as previously mentioned, the FAA Reauthorization Act of 2018 required PHMSA to harmonize the HMR with emergency amendments to the 2015-2016 edition of the ICAO TI. Special Provision A334 was not part of these emergency amendments to the 2015-16 edition but rather part of the Supplement to the ICAO TI that provides non-binding guidance to competent authorities (e.g., State of Origin) on approval requirements. Therefore, PHMSA is choosing to use the non-binding guidance offered in Special Provision A334 as part of the approval process already in place in § 173.185(h) and not specifically codify the Special provision A334 non-binding guidance into the HMR.

F. Fire Resistant Containers and Fire Containment Covers Effectiveness

UPS commented that the IFR preamble language ineffectively portrayed the effectiveness of Fire Resistant Containers (FRCs) and Fire Containment Covers (FCCs). Specifically, UPS stated that the FRC tests used preliminary container configurations and containers altered from the specification, and while important steps, the tests were not a final assessment. Furthermore, UPS commented that they have quantifiable data that demonstrates FRC and FCC effectiveness as shipping devices for lithium ion batteries, especially when it is combined with a multi-layered approach to safety measures.

PHMSA appreciates this feedback from UPS and agrees that testing is continuously ongoing, and the current state of results is not intended to be an indication of the final assessment in ensuring the safe transportation of lithium ion batteries by aircraft. PHMSA looks forward to continuing to work with UPS and any other industry partners to better enhance safety through measures such as performance packaging while ensuring continued efficient operations in lithium battery transportation and appreciates any data that can be shared that will help inform decision-making.

G. Miscellaneous Comments

PHMSA received several additional comments on various subjects, which are discussed as follows.

Mr. Kevin McAuley requested clarification on whether the provisions of the IFR prohibited lithium batteries from being transported as cargo on passenger and cargo aircraft or whether the prohibition only applied to lithium ion batteries transported above a 30 percent SOC on cargo aircraft. The IFR and this final rule prohibit lithium ion cells and batteries from being offered *as cargo* on passenger aircraft (emphasis added). Further, regarding carriage on cargo aircraft, consistent with international standards, this rulemaking prohibits lithium ion cells and batteries from being offered as cargo on cargo aircraft above a 30 percent SOC. Finally, when smaller lithium cells and batteries (both ion and metal) are offered as cargo on cargo-only aircraft, they are limited to one package per consignment as provided in § 173.185(c)(4)(iii).

AACA supported an automatic approval system, particularly for Alaska and other states where the population is less than 25 people per square mile, noting that other agencies have provided special exemptions based on that population density. PHMSA is not implementing an automatic approval in response to this comment, which is not mandated under § 333(b) of the FAA Reauthorization Act of 2018. However, while PHMSA has worked to streamline the approval process over the years, such as approval submissions being accepted via an online

portal, PHMSA continues to look for new ways to improve this process. PHMSA looks forward to working with AACA and other stakeholders in the future to continue to identify new and improved avenues to expedite the approval process.

AACA also commented on the need for additional allowances for shipments of larger quantities of lithium ion and metal batteries by aircraft, particularly to remote areas. PHMSA understands that there may be additional unique transport circumstances beyond the scope of § 173.185(g). While scenarios outside of § 173.185(g) are not identified, PHMSA can facilitate shipments of lithium batteries through the issuance of an approval under § 173.185(h) or a special permit and urges those persons offering these large shipments to apply.

An anonymous commenter requested that PHMSA add new paragraph § 173.185(a)(4), which would contain the SOC limitation (specifically, the commenter suggested: “For [transport] by air only, lithium ion cells or batteries, [except] when they are contained in equipment, shall not exceed [SOC] 30%.”). PHMSA added Special Provision A100 to the list of special provisions in § 172.102 and assigned it to the entry for “UN3480, Lithium ion batteries” in Column (7) in the § 172.101 Hazardous Materials Table (HMT). This special provision specifies that lithium ion cells and batteries must be offered for transportation at a SOC that does not exceed 30 percent of their rated capacity. Adding the SOC limitation to § 173.185(a) is not necessary and would create confusion because § 173.185(a)(1) details the classification requirements for all lithium cells or batteries, regardless of the United Nations (UN) Identification number, mode of transportation, or if shipped separately or contained in or packed with equipment. Furthermore, placement of the requirement in the HMR as a special provision is consistent with its applicability only to the air mode.

IV. Section-by-Section Review

The following is a section-by-section review of the amendments adopted in this final rule:

Part 107

Section 107.705

Section 107.705 details the requirements for an approval application. PHMSA adds paragraph (b)(6) to specify that an applicant applying for an approval for lithium cells and batteries for medical devices, as authorized in § 173.185(g), must include details on the extent to which the destination(s) of the lithium cells and batteries are not serviced daily by cargo aircraft. See “Section II.E IFR Comment Discussion; Exception for Medical Devices” for additional discussion on this revision. In addition, PHMSA revises paragraphs (b)(4) and (5)(ii) editorially to account for the new paragraph.

Section 107.709

This section includes the processing requirements for approvals. Paragraph (b) specifies PHMSA’s process for reviewing approval applications, including the time frame for requesting additional information. Paragraph (f) specifies that PHMSA will notify the approval applicant in writing of the decision on the application. PHMSA revises paragraphs (b) and (f) to detail the expedited review process for § 173.185(g) shipments of lithium cells and batteries specifically used for medical devices. PHMSA revises paragraph (b) to specify that there will be an expedited review. PHMSA also revises paragraph (f) to specify that for approvals of lithium cells and batteries for medical devices, as outlined in § 173.185(g), the approvals will be either granted or denied no later than 45 days after receipt of a completed application. See “Section II.E IFR Comment Discussion; Exception for Medical Devices” for additional discussion on this revision.

Part 171

Section 171.12

This section details the requirements for the transportation of hazardous materials throughout North America. Specifically, paragraph (a) provides allowances for the shipment of hazardous materials in accordance with the Transport Canada TDG Regulations.

Paragraph (a)(6) details additional requirements when lithium metal cells and batteries are transported in accordance with the TDG regulations. COSTHA and PRBA both commented that PHMSA did not revise § 171.12(a)(6) to reflect the newly adopted provisions that lithium ion cells and batteries were forbidden for transportation aboard passenger aircraft. PHMSA agrees with the commenters as this was an unintentional omission. Therefore, PHMSA amends § 171.12(a)(6) to add an indication that lithium ion cells and batteries (UN3480) are prohibited for transport as cargo aboard passenger aircraft.

Additionally, PHMSA revises paragraph (a)(6) to add a reference to § 173.185(c)(1)(vi). As discussed in “Section III. Section-by-Section Review; Section 173.185,” PHMSA revises § 173.185(c)(1)(vi) to add a requirement that when a package is marked or labeled in accordance with §§ 173.185(c)(1)(iii) or (iv) and is placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack. This requirement addresses a hazard communication safety gap and ensures that the overpack includes the same hazard information as displayed on the package. Therefore, to ensure this requirement also applies to shipments transported in accordance with the TDG regulations, PHMSA adds a cross reference to § 173.185(c)(1)(vi).

Section 171.24

This section provides additional requirements for the use of the ICAO Technical Instructions. COSTHA, MDBTC, and PRBA noted that PHMSA did not revise § 171.24(d)(1)(ii) to reflect the IFR provisions, specifically the prohibition of lithium ion cells and batteries from

being transported aboard passenger aircraft and the requirement in § 173.185(c)(1)(iii) to mark the outside of a package containing smaller lithium ion cells and batteries (i.e., Packaging Instruction 965, Section II) with a mark or label that indicates the package is forbidden for transport aboard passenger aircraft. This was an unintentional omission. PHMSA agrees with the commenters and makes the conforming amendment in § 171.24(d)(1)(ii) to reflect the prohibition and hazard communication requirement.

PHMSA also received comments that PHMSA add an alternative forbidden for passenger aircraft marking in § 173.185(c)(1)(iii) (i.e., “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”). Since PHMSA allows this alternative in § 173.185(c)(1)(iii), for consistency, PHMSA adds this marking alternative in § 171.24(d)(1)(ii) to allow packages containing smaller lithium cells and batteries of both chemistries to be appropriately marked. See “Section II.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft” for further discussion.

Lastly, PHMSA revises paragraph (d)(1)(ii) to specify that when a package that is marked or labeled with an indication that the package is forbidden for transport aboard passenger aircraft and is placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack. As discussed in “Section III. Section-by-Section Review; Section 173.185,” PHMSA revises § 173.185(c)(1)(vi) to add this requirement to address a hazard communication safety gap and ensure that the overpack also communicates that it is forbidden for transport on passenger aircraft. Therefore, to ensure this requirement also applies to shipments transported in accordance with the ICAO Technical Instructions, PHMSA adds the same requirement to § 171.24.

Section 171.25

This section provides additional requirements for use of the IMDG Code. COSTHA, MDBTC, PRBA, Infotrac, and Ms. Sandra Harding commented that PHMSA did not revise

§ 171.25(b)(3) to reflect the IFR provisions in § 173.185(c)(1)(iii) to require a mark or label that indicates a package of smaller lithium ion cells or batteries transported in accordance with Special Provision 188 is forbidden for transportation on passenger aircraft. This was an unintentional omission. PHMSA agrees with the commenters and is making the conforming amendment in § 171.25(b)(3) to reflect the prohibition and hazard communication requirement.

PHMSA also received comments that requested PHMSA add an alternative forbidden for passenger aircraft marking in § 173.185(c)(1)(iii) (i.e., “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”). Since PHMSA allows this alternative in § 173.185(c)(1)(iii), for consistency, PHMSA adds this marking alternative in § 171.25(b)(3) to allow packages containing smaller lithium cells and batteries of both chemistries to be appropriately marked. See “Section II.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft” for further discussion.

Lastly, PHMSA revises paragraph (b)(3) to specify that when a package that is marked or labeled with an indication that the package is forbidden for transport aboard passenger aircraft and is placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack. As discussed in “Section III. Section-by-Section Review; Section 173.185,” PHMSA revises § 173.185(c)(1)(vi) to add this requirement to address a hazard communication safety gap and ensure that the overpack also communicates that it is forbidden for transport on passenger aircraft. Therefore, to ensure this requirement also applies to shipments transported in accordance with the IMDG Code, PHMSA adds the same requirement to § 171.25.

Part 172

Section 172.101

This section outlines the HMT and instructions for its use. PHMSA received no comments to the amendments. The IFR amendments met the requirements of Section 333 of the

FAA Reauthorization Act of 2018, harmonize with international standards, and ensure the safe transportation of lithium batteries. Accordingly, no changes are being made to § 172.101.

Section 172.102

This section lists special provisions applicable to specific hazardous materials, as listed in Column (7) of the § 172.101 HMT. PHMSA received no comments to the amendments. The IFR amendments met the requirements of Section 333 of the FAA Reauthorization Act of 2018, harmonize with international standards, and ensure the safe transportation of lithium batteries.

PHMSA added a new special provision A100, assigning it to “UN3480, Lithium ion batteries, *including lithium ion polymer batteries*, 9.” This new special provision, consistent with the ICAO Technical Instructions, requires that when lithium ion cells and batteries are offered for transportation by cargo aircraft, they may not be shipped at a SOC that exceeds 30 percent of their rated capacity. Lithium ion cells and batteries may be offered for transportation at a SOC greater than 30 percent only with the approval of the Associate Administrator. This special provision does not apply to those lithium ion cells and batteries packed with or contained in equipment.

PHMSA received an anonymous comment that requested PHMSA add the SOC limitation (currently specified in special provision A100) in a new paragraph § 173.185(a)(4). It is unclear whether the commenter requested the removal of special provision A100 or the addition of a statement of the SOC limitation in § 173.185(a)(4). As discussed in “Section II.G IFR Comment Discussion; Miscellaneous Comments,” PHMSA disagrees with the commenter that it would provide further clarification to a shipper. Furthermore, special provision A100 aligns with ICAO Technical Instructions and ensures the safe transportation of lithium ion batteries on cargo aircraft (see “Section V.B. State of Charge Requirement” of the IFR for a more detailed discussion of the positive impacts to transportation at a reduced state of charge). As such, PHMSA maintains special provision A100 as written.

Part 173

Section 173.185

This section prescribes the packaging requirements for the transportation of lithium batteries. PHMSA adopted a new definition for “medical device” in the introductory paragraph, as defined in the FAA Reauthorization Act of 2018. As previously detailed, PHMSA adopted the definition of a medical device from section 333(b)(3) of the FAA Reauthorization Act of 2018 to mean “an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent, including any component, part, or accessory thereof, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, of a person.” PHMSA did not receive any comments related to this definition. PHMSA maintains that this definition provides regulatory clarity in the applicability of § 173.185(g), which aids in increased regulatory compliance and thus, safety. In addition, PHMSA maintains the definition as defined in the FAA Reauthorization Act of 2018, and no changes are being made to the “medical device” definition.

Section 173.185(a) details classification criteria for lithium cells and batteries, including the requirements for testing lithium batteries and documenting those test requirements. As previously discussed, an anonymous commenter suggested that PHMSA add a new paragraph (a)(4) to detail SOC limitation requirements. PHMSA disagrees that this new paragraph would add clarity, as the SOC limitation only applies to lithium ion cells and batteries transported by cargo aircraft (i.e., UN3480 assigned to special provision A100) and paragraph (a) applies to the transportation of all lithium cells and batteries, including those packed with and contained in equipment, by all modes. Therefore, no new paragraph is added to specify the lithium ion cell and battery SOC limitation. See “Section III. IFR Comment Discussion; Miscellaneous Amendments” for a further additional discussion on this comment.

Paragraph (c) specifies exceptions for smaller lithium cells and batteries. Paragraph (c)(1)(iii) details requirements for marking of packages with an indication that they are forbidden for transport aboard passenger aircraft or labeling of packages with the CAO label. Prior to the IFR, this paragraph only applied to smaller lithium metal cells and batteries, except when lithium metal cells or batteries are packed with or contained in equipment in quantities not exceeding 5 kg net weight. To align with the provision restricting lithium ion cells and batteries from being transported on passenger aircraft, PHMSA revised § 173.185(c)(1)(iii) to include smaller lithium ion cells and batteries in the requirement. PHMSA received several comments that requested PHMSA revise the hazard communication requirement to apply only to shipments of smaller lithium ion cells and batteries intended for transportation via aircraft, all or in part.

Alternatively, commenters requested that PHMSA provide for a delayed compliance date (i.e., a transition period) for shipments of smaller lithium ion cells and batteries offered by modes other than aircraft as well as exercise enforcement discretion. Although PHMSA acknowledges this requirement is burdensome on persons who offer smaller lithium ion cells and batteries by modes other than aircraft, PHMSA determined that this hazard communication requirement across all modes ensures that smaller lithium ion cells and batteries are not accidentally or unintentionally offered for transportation as cargo on passenger aircraft. As previously mentioned in the IFR, the potential for an uncontrolled fire involving a relatively small quantity of lithium batteries to lead to a catastrophic failure of the airframe, the inability of the package or the aircraft fire suppression system to control such a fire presents an unacceptable safety risk. This ultimately increases safe transportation as it reduces the potential for incidents involving lithium ion cells and batteries to occur aboard passenger aircraft. See “Section III.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft” and “Section III.C IFR Comment Discussion; Compliance Date” for a more detailed discussion on both issues.

PHMSA also received comments from PRBA, Infotrac, MDBTC, COSTHA, RILA, and an anonymous commenter asking that PHMSA add an alternative text marking in

§ 173.185(c)(1)(iii). This alternative (i.e., “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”) does not specify lithium battery chemistry. Because both lithium ion and lithium metal cells and batteries are now forbidden from transportation as cargo on passenger aircraft, it is not necessary to distinguish the battery chemistry as part of the marking requirement. This also provides greater flexibility with marking options for packages containing batteries of both chemistries without reducing safety. PHMSA agrees with the commenters and amends § 173.185(c)(1)(iii) to include the alternative marking.

Paragraph (c)(1)(iv) authorizes increased size limits for the paragraph (c) exceptions when the package is offered for highway or rail only and the outer package is marked with “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.” As previously discussed, RILA commented about the potential confusion in whether the § 173.185(c)(1)(iii) mark was also required when a package bears this § 173.185(c)(1)(iv) mark. As the paragraph (c)(1)(iv) mark is more conservative than the paragraph (c)(1)(iii) mark or label, PHMSA adds language in § 173.185(c)(1)(iv) to clarify that the § 173.185(c)(1)(iii) mark is not required. See “Section II. Comment Discussion; Marking Requirements for Modes other than Aircraft” for additional discussion on this change.

In final rule HM-215O,¹⁰ PHMSA added a new paragraph (c)(3)(iii) to specify overpack requirements for a package displaying a lithium battery mark. Specifically, when those packages are placed in an overpack and the lithium battery mark is not visible, the mark must be reproduced on the overpack and be marked with the word “OVERPACK” at least 12 mm (0.47 inches) high. In development of this final rule, PHMSA noted that the HM-215O overpack requirement did not include all hazard communication that could potentially be displayed on a package of smaller lithium cells or batteries. Specifically, this requirement does not include requiring the hazard communication in paragraphs (c)(1)(iii) and (iv) (i.e., the CAO label, the paragraph (c)(1)(iii) mark, and the paragraph (c)(1)(iv) mark) to be visible or reproduced on an

¹⁰ 85 FR 27810 (May 11, 2020).

overpack. As previously discussed, there is a safety need to require the paragraph (c)(1)(iii) hazard communication on all packages of smaller lithium cells and batteries, even if they are not being offered for transportation by air. This need also applies to the paragraph (c)(1)(iv) mark. The requirement to reproduce the hazard communication on the overpack is consistent with the general overpack requirements in § 173.25 specify that when a package is placed in an overpack, the proper shipping name, identification number, and labels on the package must be displayed on the overpack, unless they are otherwise visible. The overpack requirement ensures that the hazard communication that needs to be displayed on packages is not lost when consolidated or further packed in an overpack. Although not originally included, PHMSA determines that when a package bears the paragraph (c)(1)(iii) and (iv) required mark or label, and the package is placed in an overpack, those marks and labels should be visible or must be reproduced on the outside of the overpack. This is consistent with the requirements to reproduce the required markings and CAO label in § 173.185(c)(4)(ii). To address this safety gap, PHMSA redesignates current paragraph (c)(1)(vi) to paragraph (c)(1)(vii) and adds a new paragraph (c)(1)(vi) to specify the overpack requirements. PHMSA expects that this new requirement will reduce the potential for packages of smaller lithium cells or batteries that have been overpacked to be placed on a passenger aircraft and thereby increasing safety of transportation.

Section 173.185(c)(4)(i) details the quantity limitations for smaller lithium cells and batteries offered by air transportation. PHMSA received comments from COSTHA and an anonymous commenter that § 173.185(c)(4)(i) could be misinterpreted to also require that the limitations in the paragraph apply to lithium batteries packed with or contained in equipment. The commenters suggested PHMSA add “except when packaged with or contained in equipment” to the text of § 173.185(c)(4)(i). PHMSA agrees with the commenters that this provides greater clarity and harmonizes with the ICAO Technical Instructions. Therefore, PHMSA amends § 173.185(c)(4)(i) to reflect that these conditions and limitations do not apply to batteries packed with or contained in equipment.

An anonymous commenter also recommended that PHMSA add a sentence to the end of paragraph (c)(4)(i) to indicate which paragraphs lithium cells and batteries packed with or contained in equipment are subject to. PHMSA disagrees with this suggestion and expects that such addition would cause additional confusion as paragraph (c)(4)(i) does not apply to smaller lithium cells and batteries packed with or contained in equipment.

Section 173.185(c)(4)(ii) details requirements for transportation of smaller lithium cells and batteries in overpacks. The IFR amended § 173.185(c)(4)(ii) to indicate that only one package of smaller lithium cells and batteries may be placed in an overpack, consistent with ICAO Technical Instructions. PRBA, COSTHA, and MDBTC commented that the reference to only paragraph (c)(4) makes § 173.185(c)(4)(ii) inconsistent with the ICAO Technical Instructions, as lithium cells and batteries packed with or contained in equipment are not limited to one package per overpack. The commenters suggested PHMSA amend the section to instead reference paragraph (c)(4)(i) to distinguish that the requirement only applies to smaller lithium cells and batteries. PHMSA agrees, this was an error. Therefore, PHMSA revises the reference to indicate the requirement only applies to those packages prepared in accordance with § 173.185(c)(4)(i). Furthermore, an anonymous commenter suggested PHMSA delete the requirement completely from the paragraph. The commenter did not specify the reason for removing this requirement. As this provision increases the safe transportation of lithium batteries by air and meets the intent of this rulemaking to align the HMR with ICAO Technical Instructions, PHMSA will not remove the requirement in paragraph (c)(4)(i).

PHMSA expanded the overpack marking requirement in § 173.185(c)(4)(ii) to require that when a package displays the paragraph (c)(1)(iii) required mark or label and is placed in an overpack, the mark or label must be reproduced if not visible through the overpack. However, as previously discussed, in § 173.185(c)(1)(vi), PHMSA adds a requirement that when a package displays the paragraph (c)(1)(iii) required mark or label (as well as the paragraph (c)(1)(iv) mark) and is placed in an overpack, the mark or label must be visible or reproduced on overpack. This

applies to all modes of transportation and not just air. Additionally, in the HM-215O final rule, PHMSA added § 173.185(c)(3)(iii) to require that for all modes of transportation, when a package displays the lithium battery mark and is placed in an overpack, the mark must be visible or reproduced on the overpack along with the word “OVERPACK.” As both of these requirements apply to all modes of transportation, including air, the second and third sentence of paragraph (c)(4)(ii) are now duplicative. Therefore, PHMSA removes the duplicative requirement in the second and third sentence of paragraph (c)(4)(ii) to eliminate any potential regulatory confusion and increase regulatory compliance.

PHMSA added § 173.185(c)(4)(iii) to specify that a shipper is not permitted to offer more than one package of smaller lithium cells and batteries in any single consignment by aircraft. PHMSA maintains that this requirement aligns the HMR with the ICAO Technical Instructions and increases safety. However, PRBA, COSTHA, MDBTC, and an anonymous commenter noted that the amendments may have unintentionally subjected smaller lithium cells and batteries contained in or packed with equipment to this requirement. PHMSA did not intend the limitation to apply to smaller lithium cells and batteries contained in or packed with equipment, and therefore amends § 173.185(c)(4)(iii) to state that the limitation of one package in any single consignment is only for those packages prepared in accordance with the provisions of paragraph (c)(4)(i).

PHMSA added paragraph (c)(4)(v) to indicate that packages and overpacks of smaller lithium cells and batteries must be offered separately from cargo not subject to the HMR and must not be loaded into a unit load device before being offered to the operator. This paragraph harmonizes with ICAO Technical Instructions and increases safety. PHMSA received comments from PRBA, COSTHA, MDBTC, and an anonymous commenter to revise the reference from “prepared in accordance with paragraph (c)(4)” to “prepared in accordance with paragraph (c)(4)(i)” to ensure that this requirement does not apply to smaller lithium cells and batteries packed with or contained in equipment. PHMSA agrees and did not intend to require that smaller

lithium cells and batteries packed with or contained in equipment be subject to this requirement.

Therefore, PHMSA revises the reference to read as paragraph (c)(4)(i).

To account for redesignated paragraph (c)(1)(iv) and new paragraph (c)(1)(v), PHMSA redesignated paragraph (c)(4)(iv) to paragraph (c)(4)(vi). This paragraph details quantity limitations for smaller lithium cells and batteries packed with or contained in equipment. MDBTC commented that PHMSA should revise this paragraph to specify “spare sets” instead of “spares” to harmonize more accurately with the ICAO Technical Instructions. PHMSA agrees and this revision was already made in the HM-215O final rule. Therefore, no revisions to this paragraph are needed.

To account for new paragraph (c)(4)(v) and redesignated paragraph (c)(4)(vi), PHMSA redesignated paragraph (c)(4)(v) as paragraph (c)(4)(vii). PHMSA received no comments to this paragraph and there are no revisions to this paragraph.

Following publication of the IFR, PHMSA added paragraph (c)(4)(viii) in the HM-215O final rule to specify that for air transport, smaller lithium cells and batteries may not be placed in the same package as other hazardous materials. Furthermore, packages that contain smaller lithium cells and batteries must not be placed into an overpack with packages that contain materials of Class 1 (explosives) other than Division 1.4S, Division 2.1 (flammable gases), Class 3 (flammable liquids), Division 4.1 (flammable solids) or Division 5.1 (oxidizers). Upon review, PHMSA identified that paragraph (c)(4)(viii) inadvertently referenced packages prepared in accordance with paragraph (c)(4) and not paragraph (c)(4)(i). PHMSA intended that this requirement apply only to packagings of smaller lithium cells and batteries shipped by air, and not those packed with or contained in equipment. Therefore, in § 173.185(c)(4)(viii), PHMSA revises the reference of paragraph (c)(4) to paragraph (c)(4)(i) as a correcting and editorial amendment.

PHMSA added paragraph (c)(5), using text from former paragraph (c)(4)(vi). This paragraph provides minimal exceptions when the number or quantity (mass) limits in the

paragraph (c)(4)(i) table, the overpack limit described in paragraph (c)(4)(ii), or the consignment limit in paragraph (c)(4)(iii) is exceeded, but the lithium cells and batteries are still below the size limitations in paragraph (c)(3). PHMSA received an anonymous comment requesting that PHMSA remove the applicability of paragraph (c)(5) to packages that exceed the overpack limit described in paragraph (c)(4)(ii). The commenter did not provide further details to their request for this revision.

If removed, PHMSA would no longer authorize an alternative to limited exceptions when the limitation of one package of lithium cells or batteries per overpack is exceeded. In addition, this would make the regulatory provision inconsistent with the ICAO Technical Instructions, which would decrease consistency and thus, decrease compliance. Therefore, PHMSA does not remove this exception.

Lastly, PHMSA added a new paragraph (g) in the IFR to meet the mandate in the FAA Reauthorization Act of 2018. This new paragraph authorizes, with the approval of the Associate Administrator, an exception for up to two lithium batteries used for medical devices to be transported on passenger aircraft and, as applicable, at a SOC greater than 30 percent, when the intended destination of the batteries is not serviced daily by cargo aircraft. PHMSA received comments from PRBA, MDBTC, and AACA on this new paragraph. As discussed in “Section II.E Comment Discussion; Exception for Medical Devices,” no revisions to this paragraph are made.

V. Regulatory Analysis and Notices

A. Statutory/Legal Authority

This final rule is published under the authority of the Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101-5127). Section 5103(b) of the HMTA authorizes the Secretary of Transportation to “prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.” The Secretary

has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b). Lithium cells and batteries are designated as hazardous materials under 49 USC 5103(a).¹¹ This final rule revises regulations for the safe transport of lithium cells and batteries by air and the protection of aircraft operators and the flying public.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866 (“Regulatory Planning and Review”)¹² recommends that agencies assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Agencies should consider quantifiable measures and qualitative measure of costs and benefits that are difficult to quantify. Further, Executive Order 12866 recommends that agencies maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach. Similarly DOT Order 2100.6A (“Rulemaking and Guidance Procedures”) requires that regulations issued by PHMSA and other DOT Operating Administrations should consider an assessment of the potential benefits, costs, and other important impacts of the regulatory action and should quantify (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit “significant regulatory actions” to the Office of Management and Budget (OMB) for review. This rulemaking is not considered a significant regulatory action under section 3(f)(1) under Executive Order 12866 and, therefore, was not formally reviewed by OMB. Furthermore, the final rule is not considered an economically significant regulatory action under Section 3(f)(1). The final rule is not estimated to have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity,

¹¹ Hazardous materials table entries added for lithium batteries in a December 21, 1990 final rule [55 FR 52402].

¹² 58 FR 51735 (Oct. 4, 1993).

competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. Lastly, this rulemaking is also not considered a significant rule under DOT Order 2100.6A.

In promulgating this final rule, PHMSA maintains the safety provisions adopted in the IFR, while revising further the lithium battery transport regulations to ensure prohibited lithium battery packages are not transported as cargo on passenger aircraft and ensure better understanding of the requirements to achieve compliance with these provisions. In the absence of this rulemaking, potential benefits may not be gained, including increased air transportation safety and transportation efficiency. These benefits are described qualitatively in the final RIA, which is posted in the rulemaking docket. The costs of this final rule, which are estimated relative to a baseline of IFR regulatory compliance, are qualitatively and quantitatively described in the final RIA. These main costs are attributed to the cost of reproducing the §§ 173.185(c)(i)(iii) or (iv) mark or label on the outside of an overpack, when a package bearing such mark or label is placed in an overpack and the appropriate mark or label is not visible. Based on the analysis described in this final RIA, at the mean, PHMSA estimates the present value costs of the final rule are estimated at \$0.2 million annualized (at a 7 percent discount rate).

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (“Federalism”)¹³ and its implementing Presidential Memorandum (“Preemption”).¹⁴ Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in development of regulatory policies that may have “substantial direct effects on the states, on the relationship between the national government and

¹³ 64 FR 43255 (Aug. 4, 1999).

¹⁴ 74 FR 24693 (May 22, 2009).

the states, or on the distribution of power and responsibilities among the various levels of government.”

This rulemaking may preempt state, local, and Native American Tribe requirements, but does not amend any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

The Federal hazmat law contains an express preemption provision at 49 U.S.C.5125(b) that preempts state, local, and tribal requirements on certain covered subjects, unless the non-federal requirements are “substantively the same” as the federal requirements, including the following:

- (1) the designation, description, and classification of hazardous material;
- (2) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;
- (3) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;
- (4) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and
- (5) the design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This rule addresses subject items (2) and (5) above, which are covered subjects, and therefore, non-federal requirements that fail to meet the “substantively the same” standard are vulnerable to preemption under the Federal hazmat law. Moreover, PHMSA will continue to make preemption determinations applicable to specific non-federal requirements on a case-by-case basis, using the obstacle, dual compliance, and covered subjects tests provided in Federal hazmat law.

Therefore, the consultation and funding requirements of Executive Order 13132 do not apply. Consistent with 49 U.S.C. 5125, this final rule will preempt any State, local, or tribal requirements concerning the subjects identified in 49 USC 5125(b)(1) unless the non-Federal requirements are “substantively the same” as the Federal requirements. In addition, this final rule does not have sufficient federalism impacts to warrant the preparation of a federalism assessment.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 (“Consultation and Coordination with Indian Tribal Governments”)¹⁵ and DOT Order 5301.1 (“Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes”). Executive Order 13175 and DOT Order 5301.1 require DOT Operating Administrations to assure meaningful and timely input from Native American Tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing “substantial direct compliance costs” or “substantial direct effects” on such communities or the relationship and distribution of power between the federal government and Native American Tribes. Because this rulemaking does not significantly or uniquely affect the communities of Tribal governments and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1 do not apply.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider whether a rulemaking would have a “significant economic impact on a substantial number of small entities” to include small business, not-for-profit organizations that are independently

¹⁵ 65 FR 67249 (Nov. 6, 2000).

owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (“Proper Consideration of Small Entities in Agency Rulemaking”)¹⁶ requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to “thoroughly review draft rules to assess and take appropriate account of the potential impact” of the rulemakings on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated webpage.¹⁷

This rulemaking has been developed in accordance with Executive Order 13272 and with DOT’s procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of rules on small entities are properly considered. This rulemaking addresses safety risks that lithium batteries present in transportation, primarily the risk to passenger aircraft, and facilitates the transportation of hazardous materials in international commerce by providing consistency with international standards. It applies to offerors and carriers of lithium batteries, some of whom are small entities. This includes lithium cell and battery manufacturers, wholesalers, and retailers. As discussed at length in the final RIA posted in the rulemaking docket, the amendments in this final rule impose minimal costs to shippers of lithium cells and batteries when offering a package of lithium cells and batteries in an overpack. However, these costs address a necessary safety gap to ensure the safety of air transportation of lithium cells and batteries. As detailed in the final RIA, PHMSA expects that these amendments will not have a significant economic impact on a substantial number of small entities. For further

¹⁶ 67 FR 53461 (Aug. 16, 2002).

¹⁷ DOT, “Rulemaking Requirements Related to Small Entities,” <https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities> (last accessed June 17, 2021).

detail, please review the final regulatory flexibility analysis in the final RIA posted in the rulemaking docket.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.8(d), PHMSA must provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests.

PHMSA has analyzed this final rule in accordance with the Paperwork Reduction Act. PHMSA currently has approved information collections under OMB Control Numbers 2137-0034, “Hazardous Materials Shipping Papers and Emergency Response Information” and 2137-0557, “Approvals for Hazardous Materials.” In response to the IFR, PHMSA did not receive any comments related to these information collections. However, for the benefit of the reader of this final rule, the IFR discussion of the estimated paperwork burden follows.

For OMB control number 2137-0034, PHMSA estimated a revision in paperwork and recordkeeping burden as a result of smaller lithium batteries being transported as fully regulated shipments. PHMSA estimated this change in shipment because of the required consignment limitation. When shipped without certain provisions in § 173.185(c), the shipments are subject to shipping papers and Notification to the Pilot in Command (NOPIC) requirements in § 175.33. PHMSA estimated that there will be an additional 28,242 shipments annually that will require a shipping paper. PHMSA also estimated that each shipping paper takes one minute and 30 seconds to complete (28,242 shipments x 90 seconds), resulting in approximately 741 additional burden hours. PHMSA did not estimate any increase in out-of-pocket costs. The NOPIC is estimated to take one (1) minute per shipment (28,242 shipments x 1 minute), which resulted in an increase of approximately 471 burden hours. PHMSA did not estimate any increase in out-of-

pocket costs. In total for this information collection, PHMSA estimated an approximate increase of 56,484 annual number of responses (28,242 shipping paper responses + 28,242 NOPIC responses) and approximate increase of 1,212 burden hours (741 shipping paper burden hours + 471 NOPIC burden hours).

For OMB control number 2137-0557, PHMSA estimated that the changes will lead to an additional 468 approval requests. This increase in approval requests resulted from the requirement that lithium ion cells and batteries, when transported by cargo aircraft, may only be shipped at greater than a 30 percent SOC under an approval by the Associate Administrator. As detailed in the IFR, PHMSA estimated that it takes approximately 40 hours to complete the paperwork portion of an approval request, resulting in 18,720 additional burden hours (468 approval requests x 40 hours per request). PHMSA did not estimate any increase in out-of-pocket costs.

A summary of the information collection changes from the rulemaking can be found below:

OMB CONTROL NUMBER 2137-0034

Annual Increase in Number of Respondents:	0.
Annual Increase in Annual Number of Responses:	56,484.
Annual Increase in Annual Burden Hours:	1,212.
Annual Increase in Annual Burden Costs:	\$0.

OMB CONTROL NUMBER 2137-0557

Annual Increase in Number of Respondents:	468.
Annual Increase in Annual Number of Responses:	468.
Annual Increase in Annual Burden Hours:	18,720.
Annual Increase in Annual Burden Costs:	\$0.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (URMA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of federal regulatory actions on state, local, and tribal governments, and the private sector. For any NPRM or final rule that includes a federal mandate that may result in the expenditure by state, local, and tribal governments, or by the private sector of \$100 million or more in 1996 dollars in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under the UMRA. As explained above, it is not expected to result in costs of \$100 million or more in 1996 dollars on either state, local, or tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rulemaking.

H. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*), requires that federal agencies analyze actions to determine whether the action would have a significant impact on the human environment. The Council on Environmental Quality implementing regulations (40 CFR parts 1500-1508) require federal agencies to conduct an environmental review considering (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process. DOT Order 5610.1C (“Procedures for Considering Environmental Impacts”) establishes departmental procedures for evaluation of environmental impacts under NEPA and its implementing regulations.

1. Need for the Action

This final rule is being promulgated in response to comments to the IFR. The final rule maintains IFR provisions including the: (1) prohibition of the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) requirement for all lithium ion cells and batteries to be shipped at not more than a 30 percent SOC on cargo-only aircraft; and (3) restriction for smaller lithium cell and battery shipments to one package per consignment or overpack. These provisions addressed safety concerns from lithium battery transportation risks and mandates from the FAA Reauthorization Act of 2018, including adding an exception, with approval from the Associate Administrator, for certain medical device lithium batteries.

This final rule provides amendments on certain IFR provisions including marking requirements. In addition, the final rule addresses a safety need by requiring that when a package of smaller lithium cells and batteries that requires a §§ 173.185(c)(1)(iii) or (iv) mark or label is placed in an overpack, the appropriate mark or label must be visible or reproduced on the overpack.

As explained in greater length in this preamble, final RIA, and in the IFR preamble, this rulemaking addresses safety concerns from lithium batteries when transported by air. PHMSA expects that the continuation of the provisions adopted in the IFR and the revisions in this final rule increase the high safety standard currently achieved under the HMR. PHMSA has evaluated each of the amendments on its own merit, as well as the aggregate impact on transportation safety from adoption of those amendments. This EA focuses on the regulatory changes specific to this final rule. The EA for the IFR is available in the rulemaking docket.¹⁸

2. Alternatives Considered

PHMSA considered the following alternatives:

¹⁸ PHMSA-2016-0014

Selected Alternative:

The Selected Alternative is the current rulemaking as it appears in this final rule. This final rule revises the IFR regulatory text to ensure the requirements more appropriately harmonize with those amendments in the ICAO Technical Instructions. In addition, PHMSA adds a requirement, to respond to an omission in the IFR, that when a package bears a §§ 173.185(c)(1)(iii) or (iv) mark or label and is placed in an overpack, the appropriate mark or label must be visible or reproduced on the overpack. The amendments included in this alternative are more fully discussed in the preamble and regulatory text section of this rulemaking. The Selected Alternative also clarifies certain marking provisions from the IFR. Also, the Selected Alternative provides more specificity about the approval process to allow certain lithium batteries for medical equipment on aircrafts.

No Action Alternative:

If PHMSA were to select the No Action Alternative, PHMSA would not make any amendments to the IFR, and current regulations remain in place. No provisions would be amended or added. The HMR would not be fully consistent with the ICAO Technical Instructions. The HMR would not be updated to provide important details for the approval process related to the transportation of lithium batteries in medical equipment.

3. Environmental Impacts

Selected Alternative:

PHMSA anticipates that overall, the changes under the Selected Alternative increase the high safety standards currently achieved in the HMR. PHMSA expects that proper harmonization of the HMR with the ICAO Technical Instructions for lithium battery transportation will result in greater protection of human health and the environment by further decreasing the likelihood that an unauthorized package containing lithium batteries could be shipped via cargo or passenger

aircraft, which could potentially cause a dangerous incident in air travel. In addition, this harmonization is expected to capture economic and logistic efficiencies gained from avoiding shipping delays and reshipments associated with having to comply with divergent U.S. and international regulatory requirements for transportation of lithium batteries by aircraft. These delays and reshipments can have incremental environmental impacts. In addition, PHMSA expects that ensuring visibility of the markings and labels reduces the risk of harm to human safety and environmental resources from an incident caused by lithium batteries on an aircraft.

PHMSA expects that the Selected Alternative could realize modest reductions in greenhouse gas (GHG) emissions because the differences in the current HMR and the ICAO Technical Instructions for the transportation of lithium batteries absent the changes made in this final rule could potentially result in delays or interruptions. PHMSA anticipates that the No Action Alternative could result in modestly higher GHG emissions from some combination of (1) transfer of delayed hazardous materials to and from interim storage, (2) return of improperly shipped materials to their point of origin, or (3) reshipment of returned materials. The Selected Alternative reduces the inconsistencies from the divergence of the HMR and the ICAO Technical Instructions for lithium battery transportation by air and thus, avoids potential transportation inefficiencies. However, PHMSA is unable to quantify any GHG emissions benefits because of the difficulty in estimating or identifying the quantity or characteristics of such interim storage or returns/reshipments. The only potential environmental impact associated with the Selected Alternative would result from the production of additional markings or labels that must be affixed to the any overpack when the original marking or label is not visible through the overpack. The impact would be extremely minimal.

Lastly, the Selected Alternative would avoid any adverse impacts for minority populations, low-income populations, or other underserved and other disadvantaged

communities resulting from the potential shipping delays because of the divergence between the HMR and the ICAO Technical Instructions for lithium battery shipments.

No Action Alternative:

Under the No Action Alternative, current regulations would remain in place, and PHMSA would not make additional amendments to the HMR related to the air transportation of batteries to fully achieve the purpose of the IFR. Not adopting the amendments that clarify and address a potential hazard communication gap in this final rule under the No Action Alternative would allow an unintentional gap in marking requirements to persist, which could make it more like that a prohibited package could be offered for transportation on a passenger aircraft.

Additionally, efficiencies gained through proper harmonization in updates to transport standards would not be realized. Foregone efficiencies in the No Action Alternative include freeing up limited resources to concentrate on air transport hazard communication issues of potentially greater environmental impact.

4. Agencies Consulted

PHMSA has coordinated with the FAA, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the U.S. Coast Guard in the development of this rulemaking. The final rule has also been made available to other federal agencies within the interagency review process consistent with Executive Order 12866.

5. Finding of No Significant Impact

The adoption of the Selected Alternative's regulatory amendments enhances the safe and secure transportation of lithium batteries by aircraft, thereby reducing the risks of an accidental or intentional release of hazardous materials that could result in a catastrophic incident on an aircraft, potential loss of life and subsequent environmental damage. Furthermore, PHMSA

expects that the Selected Alternative will avoid adverse safety, environmental justice, and GHG emissions impacts of the No Action Alternative. Therefore, PHMSA finds that the final rule amendments would have no significant environmental impacts on the human environment.

I. Executive Order 12898

Executive Orders 12898 (“Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”),¹⁹ 13985 (“Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”),²⁰ 13990 (“Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis”),²¹ 14008 (“Tackling the Climate Crisis at Home and Abroad”),²² and DOT Order 5610.2C (“Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”) require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and other underserved and disadvantaged communities.

PHMSA has evaluated this final rule under the above Executive Orders and DOT Order 5610.2C and expects it would not cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And insofar as PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials

¹⁹ 59 FR 7629 (Feb. 11, 1994).

²⁰ 86 FR 7009 (Jan. 20, 2021).

²¹ 86 FR 7037 (Jan. 20, 2021).

²² 86 FR 7619 (Feb. 1, 2021).

generally, PHMSA does not expect the amendments would entail disproportionately high adverse risks for minority populations, low-income populations, or other underserved and other disadvantaged communities.

The final rule could reduce risks to minority populations, low-income populations, or other underserved and other disadvantaged communities. Insofar as the HMR amendments could avoid the release of hazardous materials, the final rule could reduce risks to populations and communities—including any minority, low-income, underserved, and other disadvantaged populations and communities—in the vicinity of interim storage sites and transportation arteries and hubs. Additionally, as explained in the above discussion of NEPA, PHMSA expects that the final rule amendments will yield modest GHG emissions reductions, thereby reducing the risks posed by anthropogenic climate change to minority, low-income, underserved, and other disadvantaged populations, and communities.

J. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>. DOT’s complete Privacy Act Statement can be reviewed in the *Federal Register* published on April 11, 2000,²³ or on DOT’s website at <http://www.dot.gov/privacy>.

K. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (“Promoting International Regulatory Cooperation”)²⁴ requires that agencies must consider whether the impacts associated with significant variations between

²³ 65 FR 19475 (Apr. 11, 2000).

²⁴ 77 FR 26413 (May 1, 2012).

domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreements Act (Pub. L. 103-465), prohibits federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public, and we have assessed the effects of the rulemaking to ensure that it does not cause unnecessary obstacles to foreign trade. In this case, the final rule further harmonizes U.S. lithium battery provisions with the ICAO Technical Instructions so as to reduce regulatory burdens and minimize delays arising from having to comply with divergent regulatory requirements. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

L. Executive Order 13211

Executive Order 13211 ("Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use")²⁵ requires Federal agencies to prepare a Statement of

²⁵ 66 FR 28355 (May 22, 2001).

Energy Effects for any “significant energy action.” Executive Order 13211 defines a “significant energy action” as any action by an agency (normally published in the Federal Register) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy (including a shortfall in supply, price increases, and increased use of foreign supplies); or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action.

This final rule is a non-significant action under Executive Order 12866, and PHMSA expects it to have an annual effect on the economy of less than \$100 million. Further, this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy in the United States. The Administrator of OIRA has not designated the final rule as a significant energy action. For additional discussion of the anticipated economic impact of this rulemaking, please review the final RIA posted in the rulemaking docket.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

In consideration of the foregoing, PHMSA amends 49 CFR chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

1. The authority citation for part 107 is amended to read as follows:

Authority: 49 U.S.C. 5101-5128, 44701; Pub. L. 101-410 Section 4; Pub. L. 104-121 Sections 212-213; Pub. L. 104-134 Section 31001; Pub. L. 114-74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

2. In § 107.705, revise paragraphs (b)(4) and (b)(5)(ii) and add paragraph (b)(6) to read as follows:

§ 107.705 Registrations, reports, and applications for approval.

* * * * *

(b) * * *

(4) Any additional information specified in the section containing the approval;

(5) * * *

(ii) Substantiation, with applicable analyses or evaluations, if appropriate, demonstrating that the proposed activity will achieve a level of safety that is at least equal to that required by the regulation; and

(6) For lithium cells and batteries used for a medical device and transported in accordance with § 173.185(g) of this chapter, details on the extent to which the destination(s) of the lithium cell or battery is not serviced daily by cargo aircraft.

* * * * *

3. In § 107.709, revise paragraphs (b) and (f) to read as follows:

§ 107.709 Processing of an application for approval, including an application for renewal or modification.

* * * * *

(b) The Associate Administrator will review an application for an approval, modification of an approval, or renewal of an approval in conformance with the standard operating procedures specified in appendix A of this part (“Standard Operating Procedures for Special Permits and

Approvals”). The Associate Administrator will conduct an expedited review process for shipments of lithium cells and batteries specifically used for medical devices, as outlined in § 173.185(g) of this chapter. At any time during the processing of an application, the Associate Administrator may request additional information from the applicant. If the applicant does not respond to a written request for additional information within 30 days of the date the request was received, the Associate Administrator may deem the application incomplete and deny it. The Associate Administrator may grant a 30-day extension to respond to the written request for additional information if the applicant makes such a request in writing.

* * * *

(f) The Associate Administrator notifies the applicant in writing of the decision on the application. A denial contains a brief statement of reasons. For shipments of lithium cells and batteries specifically used for medical devices, as outlined in § 173.185(g) of this chapter, an approval shall be considered and either granted or denied not later than 45 days after receipt of a completed application.

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

4. The authority citation for part 171 is revised to read as follows:

Authority: 49 U.S.C. 5101-5128, 44701; Pub. L. 101-410 section 4; Pub. L. 104-134, section 31001; Pub. L. 114-74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

5. In § 171.12, revise paragraph (a)(6) to read as follows:

§ 171.12 North American Shipments.

(a) * * *

(6) *Lithium cells and batteries.* Lithium metal cells and batteries (UN3090) and lithium ion cells and batteries (UN3480) are forbidden for transport as cargo aboard passenger-carrying aircraft. The outside of each package or overpack that contains lithium cells or batteries meeting the conditions for exception in § 173.185(c) of this subchapter and transported in accordance

with the Transport Canada TDG Regulations must be marked or labeled in accordance with § 173.185(c)(1)(iii), (iv), and (vi), as appropriate.

* * * * *

6. In § 171.24, revise paragraph (d)(1)(ii) to read as follows:

§ 171.24 Additional requirements for the use of the ICAO Technical Instructions.

* * * * *

(d) * * *

(1) * * *

(ii) *Lithium cells and batteries.* Lithium metal cells and batteries (UN3090) and lithium ion cells and batteries (UN3480) are forbidden for transport as cargo aboard passenger-carrying aircraft. The outside of each package that contains lithium metal cells or batteries transported in accordance with Packing Instruction 968, Section II or lithium ion cells or batteries transported in accordance with Packing Instruction 965, Section II must be appropriately marked:

“PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or labeled with a CARGO AIRCRAFT ONLY label as specified in § 172.448 of this subchapter.

When placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack.

* * * * *

7. In § 171.25, revise paragraph (b)(3) to read as follows:

§ 171.25 Additional requirements for the use of the IMDG Code.

* * * * *

(b) * * *

(3) The outside of each package containing lithium metal cells or batteries (UN3090) or lithium ion cells or batteries (UN3480) transported in accordance with special provision 188 of the IMDG Code must be appropriately marked “PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or labeled with a CARGO AIRCRAFT ONLY label as specified in § 172.448 of this subchapter. The provisions of this paragraph also apply to packages of lithium cells or batteries packed with, or contained in, equipment that exceed 5 kg (11 pounds) net weight. When placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

8. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

9. In § 173.185:

- a. Revise paragraphs (c)(1)(iii) and (iv);
- b. Redesignate paragraph (c)(1)(vi) as paragraph (c)(1)(vii);
- c. Add new paragraph (c)(1)(vi); and
- d. Revise paragraphs (c)(4)(i) introductory text and (c)(4)(ii), (iii), (v), and (viii).

The revisions and addition read as follows:

§ 173.185 Lithium cells and batteries.

* * * * *

(c) * * *

(1) * * *

(iii) Except when lithium cells or batteries are packed with or contained in equipment in quantities not exceeding 5 kg net weight, the outer package that contains lithium cells or batteries must be appropriately marked: “PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, “LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT”, or labeled with a “CARGO AIRCRAFT ONLY” label as specified in § 172.448 of this subchapter.

(iv) For transportation by highway or rail only, the lithium content of the cell and battery may be increased to 5 g for a lithium metal cell or 25 g for a lithium metal battery and 60 Wh for a lithium ion cell or 300 Wh for a lithium ion battery, provided the outer package is marked: “LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.” A package marked in accordance with this paragraph does not need to display the marking required in paragraph (c)(1)(iii) of this section.

* * * * *

(vi) When a package marked or labeled in accordance with paragraph (c)(1)(iii) or (iv) of this section is placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack.

* * * * *

(4) * * *

(i) For transportation by aircraft, lithium cells and batteries may not exceed the limits in the following Table 1 to paragraph (c)(4)(i). The limits on the maximum number of batteries and

maximum net quantity of batteries in the following table may not be combined in the same package. The limits in the following table do not apply to lithium cells and batteries packed with, or contained in, equipment.

* * * * *

(ii) Not more than one package prepared in accordance with paragraph (c)(4)(i) of this section may be placed into an overpack.

(iii) A shipper is not permitted to offer for transport more than one package prepared in accordance with the provisions of paragraph (c)(4)(i) of this section in any single consignment.

* * * * *

(v) Packages and overpacks of lithium batteries prepared in accordance with paragraph (c)(4)(i) of this section must be offered to the operator separately from cargo which is not subject to the requirements of this subchapter and must not be loaded into a unit load device before being offered to the operator.

* * * * *

(viii) Lithium cells and batteries must not be packed in the same outer packaging with other hazardous materials. Packages prepared in accordance with paragraph (c)(4)(i) of this section must not be placed into an overpack with packages containing hazardous materials and articles of Class 1 (explosives) other than Division 1.4S, Division 2.1 (flammable gases), Class 3 (flammable liquids), Division 4.1 (flammable solids), or Division 5.1 (oxidizers).

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